

REMARKS

Claims 1-6, 8-18 and 21-27 were pending in this application. Applicants have cancelled claims 1-6, 8-18, 21, 22 and 25-27, without prejudice, and reserve the right to prosecute the subject matter of the cancelled claims in one or more related applications.

Also, Applicants have amended claims 23 and 24 for purposes of clarity, and added new claims 31-41. Support for the amended claims and new claims can be found in the specification as originally filed, as indicated in the following table:

<u>New Claim</u>	<u>Support</u>
23	Page 5, lines 18-22
24	Page 5, lines 23-27
31, 32, 34, 35, 39 and 40	Page 8, lines 13-15
33, 36, 41	Page 3, lines 16-18
37	Page 5, lines 28-32; and Page 7, lines 31-32
38	Page 8, lines 3-6

No new matter has been added. Upon entry of these amendments, claims 23, 24 and 31-41 will be pending.

I. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

Claims 1-3, 13, 14 and 21-24 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,998,458 to Kaddurah-Daouk ("Kaddurah-Daouk") in view of U.S. Patent No. 4,772,591 to Meisner ("Meisner"), U.S. Patent No. 5,888,553 to Grant *et al.* ("Grant"), U.S. Patent No. 5,756,469 to Beale ("Beale '469"), and U.S. Patent No. 5,716,926 to Beale *et al.* ("Beale '926"). In response to the Amendment filed on October 23, 2006, the Examiner alleges that "the patient population defined by the 'in need therefore' have been clearly suggested, e.g., patients with osteoporosis, osteoarthritis, or periodontitis; patient with wound" (Office Action, paragraph bridging pages 5 and 6). The Examiner also alleges that "it is well settled patent law that mode of action elucidation (promote growth and mineralization of bone or cartilage, etc.) does not impart patentable moment to otherwise old and obvious subject matter" (Office Action, page 6, ¶6).

Although Applicants do not acquiesce with the rejections, solely to expedite prosecution, claims 1-3, 13, 14, 21 and 22 have been cancelled, thus rendering the rejections moot with respect to these claims.

For the following reasons, Applicants submit that amended claims 23 and 24, and new claims 31-41 are patentable over the cited references.

Amended claim 23, which recites “[a] method of improving acceptance and osseous integration of a bone implant in a subject” and “the subject in need of such improvement,” defines the patient population as those having a bone implant. Amended claim 24, which recites “[a] method for accelerating healing in a subject having a defect in bone or cartilage tissue caused by trauma or surgery” and “the subject in need thereof,” defines the patient population as those having a defect in bone or cartilage tissue caused by trauma or surgery. In order to render obvious the subject matter of each claim, the methods of Kaddurah-Daouk in view of Meisner, Grant, Beale ‘469, and Beale ‘926 must be practiced in the patient population defined by each claim.

None of the references, either alone or together, disclose, teach or suggest the administration of creatine pyruvate or an analogue thereof to a subject having a bone implant, as recited in amended claim 23. Nor do the references, either alone or together, disclose, teach or suggest the administration of creatine pyruvate or an analogue thereof to a subject having a defect in bone or cartilage tissue caused by trauma or surgery, as recited in amended claim 24. Thus, the references do not render obvious amended claims 23 and 24, as well as their new dependent claims 31-33 and 34-36, respectively.

Like amended claim 24, new claim 35 also recites “[a] method for accelerating healing in a subject having a defect in bone or cartilage tissue caused by trauma or surgery” and “the subject in need thereof,” and similarly defines the patient population as those having a defect in bone or cartilage tissue caused by trauma or surgery. As discussed above, none of the references, either alone or together, disclose, teach or suggest the administration of creatine pyruvate or an analogue thereof to a subject who has a defect in bone or cartilage tissue caused by trauma or surgery. Thus, new claim 37, and its dependent claims 38-41, are believed to be patentable over the references.

For the foregoing reasons, Applicants respectfully submit that the claim rejections be withdrawn.

CONCLUSION

Applicants respectfully request entry of the remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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Enclosures